

REMARKS

Claims 5, 10, 38-41, and 54-57 are pending in the present application.

At the outset, Applicants wish to thank Examiner Mertz for the indication that Claim 5 is allowed (paper number 18, page 7, line 8). Applicants also wish to thank Examiner Mertz for the helpful and courteous discussion with their undersigned Representative on July 1, 2003, as well as her helpful suggestions to address the current grounds of rejection. The following remarks will expand and summarize the issues discussed.

The rejection of Claims 26-57 under 35 U.S.C. §112, first paragraph (written description), is obviated in part by amendment and traversed in part.

At the outset, Applicants note that Claims 26-37 and 42-53 have been cancelled. It is requested that cancellation of these claims be without prejudice toward their presentation in a subsequent continuation application. Therefore, Applicants make no comment as to the propriety of this ground of rejection over Claims 26-37 and 42-53. The following comments pertain, therefore, to Claims 38-41 and 54-57. Certainly, Applicants wish to thank Examiner Mertz for the helpful suggestions to amend Claims 38-41 and 54-57 to place them in condition to satisfy the requirements of 35 U.S.C. §112, first paragraph.

The Office has alleged that the specification fails to provide a representative number of species to support the genus provided in the present claims (paper number 18, page 4). Applicants respectfully disagree.

Applicants direct the Examiner's attention to MPEP § 2163.02:

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

The Office asserts that “the specification and claims do not indicate what distinguishing attributes shared by the members of the genus... Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted.” (paper number 18, page 3). Applicants disagree with the Office and specifically refer the Examiner pages 10-14 and the Examples of the present application, as well as Claims 38 and 54. Contrary to the Office’s assertion, this section of the specification clearly provides an explicit description of the amino acid sequences of the protein, permissible mutations, protein activity, and methods of assessing all of the above. Moreover, Applicants note that Claims 38 and 54 do provide a clear and irrefutable nexus between structure and function, which the Examiner specifically indicates is required (paper number 18, page 3, lines 6-10).

Applicants further note that part of the basis for this ground of rejection is “The amount of experimentation required for one of ordinary skill in the art to make the claimed invention would be undue.” (paper number 18, page 3, lines 5-6). However, this statement has no basis in the written description determination under 35 U.S.C. §112, first paragraph. As stated in MPEP § 2163.02: “determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gostelli*...”.

Therefore, the present claims do clearly allow the skilled artisan to recognize what has been invented and what is claimed is adequately described in the specification within the meaning of 35 U.S.C. § 112, first paragraph.

Accordingly, withdrawal of this ground of rejection is requested.

The rejection of Claims 26-57 under 35 U.S.C. §112, first paragraph (enablement), is obviated in part by amendment and traversed in part.

At the outset, Applicants note that Claims 26-37 and 42-53 have been cancelled. It is requested that cancellation of these claims be without prejudice toward their presentation in a subsequent continuation application. Therefore, Applicants make no comment as to the propriety of this ground of rejection over Claims 26-37 and 42-53. The following comments pertain, therefore, to Claims 38-41 and 54-57. Certainly, Applicants wish to thank Examiner Mertz for the helpful suggestions to amend Claims 38-41 and 54-57 to place them in condition to satisfy the requirements of 35 U.S.C. §112, first paragraph.

MPEP § 2164.01 states:

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.”

Applicants submit that one of skill in the art could obtain a polypeptide of Claims 38-41 or Claims 54-57, which induces SHC phosphorylation or induces the SHC/MAPK pathway, based on the disclosure provided in the specification, without undue experimentation, especially when the disclosure is augmented with the information known in the art. The claims provide a clear nexus between structure and function. The specification discloses at pages 10-14 and the Examples an explicit description of the amino acid sequences of the protein, permissible mutations, protein activity, and methods of assessing all of the above. Moreover, page 2, lines 21-25 disclose the importance of Asp20 to the function of the claimed polypeptide. Further, Figure 1 provides the schematic representation (crystal structure) of the human IL-2 structure including the location of the amino acid residues encompassed by the present claims (see Figure 1 and page 4, line 25-34). Also of note is Figure 5, which shows the model of IL-2/IL-2R interactions (see Figure 5 and page 5, line

15-21). Therefore, the skilled artisan can clearly appreciate the scope of Claims 38-41 and Claims 54-57, in view of the nexus between structure and function provided in these claims and the explicit guidance proffered in the specification.

Moreover, MPEP §2164.06 states:

“... quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). " 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.' ”

Applicants submit that, in view of the guidance proffered by the present specification (and briefly summarized above), screening proteins that satisfy the threshold set forth in Claims 38-41 and 54- would require nothing more than routine skill in the art. In fact, on page 27-32, Applicants have set forth several Examples to assist the artisan in these efforts.

Therefore, the present claims are believed to be fully enabled by the specification and the common knowledge available in the art.

Withdrawal of these grounds of rejection is requested.

The rejection of Claims 10, 28-37, 38-41, and 54-57 under 35 U.S.C. §112, second paragraph (listed as “first” paragraph on page 6 of paper number 18) is obviated by appropriate amendment.

With respect to Claim 10, Applicants have replaced the phrase “DNA sequence” with the term “polynucleotide.” Accordingly, Claim 10 has proper antecedent basis in allowed Claim 5 and, therefore, should also be allowed.

Applicants have amended Claims 38-41 and 54-57 to replace the term “homologous” with the proper term “homology” as kindly suggested by the Examiner. As such, these claims are now free of the criticisms of the Examiner under 35 U.S.C. §112, second paragraph.

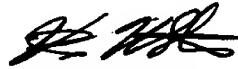
Finally, the rejection of Claims 28 and 32-37 is obviated by cancellation of these claims. Applicants note that cancellation of Claims 1-4, 6-9, 11-37, and 42-53 during examination of this application is in no way to be construed as acquiescence to the rejection. On the contrary, Applicants maintain their position on the impropriety of the rejection of these claims and wish to maintain the right to pursue examination in a subsequent continuation or divisional application. Therefore, the cancellation of Claims 1-4, 6-9, 11-37, and 42-53 in the present application serves only to meaningfully and expeditiously further examination of this application.

Withdrawal of this ground of rejection is requested.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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